ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

December 18, 2007

The Honorable Michael Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Leavitt:

We commend your leadership of the Interagency Working Group on Import Safety and appreciate the Group's Action Plan for Import Safety released in November 2007.

Recommendation 4 in the Action Plan would toughen penalties and strengthen law enforcement efforts on imports. We think the law enforcement recommendation is a positive step. Furthermore, we have learned from federal law enforcement officials that extraterritorial jurisdiction of the Food, Drug and Cosmetic Act (FDCA) needs clarification. The Action Plan does not address this point, but we believe that assuring extraterritorial application would improve the federal government's legal position vis-a-vis several of the law enforcement reforms advanced in Recommendation 4. We believe Administration support of this clarification would bolster the law enforcement recommendation in the Action Plan and improve public health protection against unsafe imports regulated by the Food and Drug Administration (FDA). It might also help to improve pending legislation in the Congress.

Over the last few years, this Committee has received testimony and information substantiating the need to make the FDCA extraterritorial jurisdiction explicit. On October 3, 2000, a witness representing the U.S. Department of Justice (one of the twelve agencies represented on the Working Group) testified before the Subcommittee on Oversight and Investigations that "amending the FDCA to make the extraterritorial application of the FDCA to persons affecting the United States by their actions abroad explicit instead of implicit would aid the investigation of criminal cases in these situations." As further stated, prosecution of these cases is difficult because much of the evidence of unlawful activity is located overseas, and thus is more difficult to obtain than evidence located within our borders. Amending the FDCA to make extraterritorial jurisdiction explicit would help to eliminate some of the obstacles that slow investigations and create questions regarding the applicability of the FDCA in these cases. This amendment would give prosecutors the explicit authority to bring cases and enforce penalties against those that violate the provisions of the FDCA abroad.

The Department of Justice continues to urge that the FDCA be amended to make explicit FDCA jurisdiction over conduct that occurs outside the United States where products subject to the FDCA are intended to be imported into the United States (see December 6, 2006, letter, attached). We also note that

the former Assistant Director for the FDA Office of Criminal Investigations testified before the Subcommittee on Oversight and Investigations on December 13, 2005, in support of legislation that would provide extraterritorial jurisdiction in the FDCA. In addition, an attorney with the Office of Consumer Litigation in the Department of Justice in a 2004 article in the Food and Drug Law Journal (see attachment) proposed the clarification:

> "[T]he FDCA should be amended to apply explicitly to foreign companies and individuals who have involved themselves with the distribution of drugs and devices in the United States. The clarification of the FDCA should be limited to conduct that directly affects the United States and consumers within the United States, subject matter that is well within accepted principles of legal jurisdiction. The application of such a law will necessarily be limited to due process considerations – U.S. law can only hold a person accountable whose conduct is tied to the United States. *The need for such a clarification is substantial.* The incentives to sell fraudulent products are considerable, and, as can be seen from the situation in the developing world, the results of such conduct could be extremely hazardous to the public health." (Emphasis added.)

The goal of Recommendation 4 in the Action Plan is to strengthen penalties and take strong enforcement actions to ensure accountability. However, the enforcement ability of the United States will continue to be hampered under the current FDCA if extraterritorial jurisdiction application of the statute is not ensured. Clarifying extraterritorial jurisdiction in the FDCA is a logical and necessary means to the Working Group's recommendation. In your capacity as the lead advisor to the President on import safety, we respectfully ask: Would you be willing to urge the Administration to support making FDCA extraterritorial jurisdiction explicit to cover conduct abroad where the United States is the ultimate destination for the products?

Your consideration and response is greatly appreciated. If your staff has any questions, please contact Mr. Alan Slobodin or Ms. Krista Carpenter of the Committee Minority staff at (202) 225-3641.

Sincerely,

Joe Barton
Ranking Member

John Shimkus
Ranking Member
Subcommittee on Oversight and Investigations

cc: The Honorable John D. Dingell, Chairman
The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations

Attachments